

STATE OF MAINE DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION MAINE BOARD OF PHARMACY 35 STATE HOUSE STATION AUGUSTA, MAINE 04333-0035

Anne L. Head, Esq. Commissioner

Geraldine L. Betts

February 24, 2014

Email: kirk.altvater@ihs.gov

First Class Mail

Certified Mail 7011 1150 0001 7011 5746 Return Receipt Requested

Kelvin N. Whitehead Pleasant Point Health Center 11 Back Road Perry ME 04667

Certified Mail 7011 1150 0001 7011 5876 Return Receipt Requested

Sandar Yarmal Pleasant Point Health Center 11 Back Road Perry ME 04667

Re: Pending Renewal Application for PH 50000192

Dear Mr. Whitehead and Ms. Yarmal:

This is to acknowledge receipt of the Pleasant Point Health Center pharmacy license renewal application received by this office on January 21, 2014.

It has come to the Board of Pharmacy's attention that neither the pharmacist in charge, Kelvin Whitehead, nor the staff pharmacist Linda Kalns, is licensed by the Board. All persons and entities engaged in the practice of pharmacy in Maine must hold an appropriate license with the Board or provide legal justification supporting exemption from that requirement. Please provide the legal justification supporting an exemption from licensure for both Mr. Whitehead and Ms. Kalns.

Licensing (207)624-8620 Main Receptionist (207)624-8603 Hearing Impaired/TTY Maine Relay 711 PRINTED ON RECYCLED PAPER
www.maine.gov/professionallicensing

Geraldine.L.Betts@maine.gov Direct Line: (207)624-8625 Fax: (207)624-8637

OFFICE LOCATION: GARDINER ANNEX 76 NORTHERN AVENUE, GARDINER, MAINE

In addition, Board of Pharmacy records do not clearly provide the organizational structure related to the operation of the pharmacy. Please identify all persons or entities that have responsibility for the operation of the pharmacy located at Pleasant Point Health Center, including information regarding ownership.

The above information is necessary to process the pending application. Please provide the requested materials no later than **March 3, 2014**, for your convenience you can email your reply to <u>pharmacy.board@maine.gov</u> or via fax to 207-624-8666.

Sincerely,

Kelly L. McLaughlin

Senior Consumer Assistant



PLEASANT POINT XEALTX CENTER

PO BOX 351 PERRY, ME 04667 TEL (207) 853-0644 FAX (207) 853-2347

http://www.wabanaki.com/health.htm

March 4, 2014

Maine Board of Pharmacy 35 State SHS Augusta, ME 04333-0035

Dear Maine Board of Pharmacy:

Attached, please find the information you had requested regarding the renewal application for PH50000192. We had to wait for official determination from Indian Health Services regarding the Indian HealthCare Improvement Act (IHCIA) language that addresses licensure exemption.

The Pleasant Point Passamaquoddy Tribal Council is the responsible owner, I am the administrator for the health department and Kelvin N. Whitehead is our Pharmacist-In-Charge. There are currently no pharmacy technicians working under Mr. Whitehead.

Again, please accept our apology for the tardiness, but understand that it often takes time when we are expected to provide information that we must obtain from the I.H.S.

Be well.

Sandra Yarmal, Director

Copy: Kirk J. Altvater, Asst. Health Director; file

(Please note the information below is contained within the Affordable Care Act)

IHCIA - Exemption from State Licensing (25 USC 1621t)

25 USCS § 1621t

§ 1621t. Licensing

Licensed health professionals employed by a tribal health program shall be exempt, if licensed in any State, from the licensing requirements of the State in which the tribal health program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.).

HISTORY:

(Sept. 30, 1976, P.L. 94-437, Title II, § 221, as added Oct. 29, 1992, P.L. 102-573, Title II, § 215, 106 Stat. 4559.)

(As amended March 23, 2010, P.L. 111-148, Title X, Subtitle B, Part III, § 10221(a), 124 Stat. 935.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Explanatory notes:

The amendment made by § 10221(a) of Act March 23, 2010, P.L. 111-148, is based on § 134(a) of Subtitle B of Title

I of S. 1790, as reported in the Senate on Dec. 16, 2009, which was enacted into law by such § 10221(a).



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Anne L. Head, Esq. Commissioner Geraldine L. Betts

April 8, 2014

Sandra Yarmal, Director Pleasant Point Health Center 11 Back Road Perry, ME 04667

Kelvin N. Whitehead Pleasant Point Health Center 11 Back Road Perry, ME 04667

Re: Pleasant Point Health Center Pharmacy License (PH50000192)

Dear Ms. Yarmal and Mr. Whitehead:

At its meeting on April 3, 2014, the Maine Board of Pharmacy ("the Board") authorized the retail independent pharmacy renewal application for Pleasant Point Health Center ("PPHC") and considered the correspondence dated February 24, 2014, from Board staff to PPHC, and PPHC's response dated March 4, 2014. Based upon the information provided that the owner of PPHC is the Pleasant Point Passamaquoddy Tribal Council and that PPHC asserts that 25 U.S.C. § 1621t provides an exemption from licensure for PPHC's pharmacists, the Board determined to provide a period of thirty (30) days from receipt of this notification for PPHC to register a Maine licensed pharmacist as the pharmacist in charge for the PPHC pharmacy.

Pursuant to Maine law, persons engaged in the practice of pharmacy within the State must hold a valid license or be exempt from licensure. 32 M.R.S. §§ 13701-13847. Because the exemption relied upon by PPHC is pursuant to a federal law enacted after October 10, 1980, and was not made specifically applicable within the State of Maine in accordance with 25 U.S.C. § 1735(b), Maine law applies. 25 U.S.C. § 1725(h); 30 M.R.S. § 6202(1). Therefore, all persons engaged in the practice of pharmacy at PPHC must hold a valid Maine license.

Licensing (207)624-8579 Main Receptionist (207)624-8603 Hearing Impaired/TTY Maine Relay 711



Geraldine.L.Betts@maine.gov Direct Line: (207)624-8625 Fax: (207)624-8666

Office Location: Gardiner Annex 76 NORTHERN AVENUE, GARDINER, MAINE

Letter to Yarmal and Whitehead April 8, 2014 Page 2

If you have any questions, please contact the Board at 207-624-8621 or pharmacy.board@maine.gov.

Sincerely,

James D. Liddell

Professional Licensing Coordinator

cc: Michael Miller, Assistant Attorney General



MAY 29 2014

Indian Health Service Nashville Area Office 711 Stewarts Ferry Pike Nashville, TN 37214-2634

Mr. James D. Liddell Professional Licensing Coordinator Maine Board of Pharmacy 35 State House Station Augusta, Maine 04333-0035

Re: Pleasant Point Health Center Pharmacy License PH50000192

Dear Mr. Liddell:

I am writing this letter in response to the April 8th letter and May 2nd e-mail sent to the Pleasant Point Health Center (PPHC) asserting that health professionals employed by PPHC must be licensed by the State of Maine by June 2, 2014, in accordance with the Maine Indian Claims Settlement Act (Settlement Act). The PPHC is operated by the Passamaquoddy Tribe at Pleasant Point under an Indian Self-Determination and Education Assistance Act (ISDEAA) contract (see 25 U.S.C. §§ 450 to 458aaa-18). Pursuant to the Indian Health Care Improvement Act (IHCIA), codified at 25 U.S.C. § 1621t, an ISDEAA contractor's health professionals can be licensed in any state. There is no requirement that PPHC's pharmacists be licensed in the State of Maine.

On February 24, 2014, the Maine Pharmacy Board (the Board) wrote PPHC stating that the Pharmacist in Charge and the staff pharmacist must be licensed by the Board or that PPHC must provide legal justification that exempts these individuals from State licensure. On March 4, 2014, PPHC sent a letter to the Board providing it with the legal justification of the federal licensure standard authorized of 25 U.S.C. § 1621t. Specifically, § 1621t states the following:

Licensed health professionals employed by a tribal health program shall be exempt, if licensed in any State, from the licensing requirements of the State in which the tribal health program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.).

On April 8, 2014, the Board informed PPHC via letter that Section 1621t did not apply in the State of Maine because the Settlement Act, codified at 25 U.S.C. § 1735(b), nullifies any law enacted after October 10, 1980, passed for the benefit of Indians, unless it is made specifically applicable in Maine. Specifically, the letter states the following, "Because the exemption relied upon by PPHC is pursuant to a federal law enacted after October 10, 1980, and was not made specifically applicable within the State of Maine in accordance with 25 U.S.C. § 1735(b), Maine law applies." Section 1735(b) states the following:

The provisions of any Federal law enacted after October 10, 1980, for the benefit of Indians, Indian nations, or tribes or bands of Indians, which would affect or preempt the application of the laws of the State of Maine, including application of the laws of the

State to lands owned by or held in trust for Indians, or Indian nations, tribes, or bands of Indians, as provided in this subchapter and the Maine Implementing Act, shall not apply within the State of Maine, unless such provision of such subsequently enacted Federal law is specifically made applicable within the State of Maine.

The Indian Health Service (IHS) disagrees with the Board's assertion that the Settlement Act invalidates § 1621t. PPHC does not rely upon a federal law enacted after October 10, 1980. The IHCIA was passed into law on September 30, 1976. Although the IHCIA has been amended by subsequent legislation, the Act itself was passed four years before the Settlement Act. Therefore, Congress did not have to specifically say that the licensure requirements of § 1621 had to specifically apply in the State of Maine.

Most importantly, § 1621t was not passed for the "benefit of Indians, Indian nations, or tribes or bands of Indians." Section 1621t was passed for the benefit of the federal government to enable it, through its ISDEAA contractors, to provide health care services to its federal beneficiaries, as mandated by Congress. Only ISDEAA contractors are authorized to rely upon § 1621t. The Settlement Act makes no mention of ISDEAA contractors, and § 1621t is only implicated by virtue of an Indian nation, tribe or band of Indians operating health programs for the federal government under an ISDEAA contract. In other words, the ISDEAA contract is a condition precedent to reliance upon § 1621t. Ultimately, the responsibility for carrying out these health care programs for Indians is the Federal Governments, in accordance with applicable federal laws.

The Board's position is frustrating efforts of the PPHC to carry-out health care activities under its federal contract. The IHCIA authorizes the public benefit of providing health care services to members of federally-recognized tribes to carry-out the United States' promises and commitments under federal law and treaties between the United States and tribal governments. See, 25 U.S.C. §§ 1601 and 1602(1)(2). Section 1621t enables ISDEAA contractors to utilize the same licensure standards as the federal government so that like the IHS, they are better enabled to recruit and hire health professionals to care for these federal beneficiaries.

The health professionals employed by PPHC are properly licensed pursuant to applicable federal law. For this reason, we respectfully request that the Board rescind its April 8th letter and terminate any disciplinary actions against PPHC and its health professionals. We are happy to discuss this matter this you.

Sincerely,

Area Director